IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CHERIE WILSON	:	**CIVIL ACTION**
Plaintiff	:	
	:	**NO. 19-1905**
v.	:	
	:	
ETHICON INC., *et al.*	:	
Defendants	:	

NITZA I. QUIÑONES ALEJANDRO, J. DECEMBER 16, 2019

MEMORANDUM OPINION

INTRODUCTION

Plaintiff Cherie Wilson filed this product liability and negligence action claiming injuries allegedly caused by defects in a TVT pelvic mesh implant device that was either designed, manufactured, sold, or distributed by Defendants Ethicon, Inc., Johnson & Johnson, Secant Medical, Inc., and/or Secant Medical, LLC (the "Secant Defendants"). This action was filed as part of the *Pelvic Mesh Litigation* in the Philadelphia Court of Common Pleas and removed to federal court. The Secant Defendants have moved to dismiss the claims asserted against them pursuant to the Biomedical Access Assurance Act (the "BAAA" or "Act"), 21 U.S.C. § 1601-1606, which provides immunity for certain biomaterials suppliers. The issues raised by the parties have been fully briefed and are ripe for disposition. For the reasons set forth, the Secant Defendants' motion is granted and the claims against the Secant Defendants are dismissed with prejudice.

BACKGROUND

The procedural and factual histories are known to the parties. Therefore, only the facts pertinent to the underlying motion will be discussed. These facts are taken primarily from the

master long form complaint filed in the initial state court proceeding and the parties' briefs on the underlying motion. To the extent that any facts are disputed, such disputes will be noted and construed in Plaintiff's favor. As noted, the Secant Defendants seek dismissal of Plaintiff's claims pursuant to the immunity provisions of the BAAA.

LEGAL STANDARD

Generally, for a complaint to survive a motion to dismiss, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). In determining the sufficiency of a complaint, the court must accept all well-pleaded factual allegations in the complaint as true and draw all inferences in favor of the non-moving party. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

Under the BAAA, however, Congress has provided a modified standard for the dismissal of a complaint. *See* 21 U.S.C. §§ 1601–1606. The Act applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." *Id.* § 1603(b)(1). It further provides that "[a] defendant may, at any time during which a motion to dismiss may be filed under applicable law, move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier" if the defendant: (1) is not "liable as a manufacturer;" (2) is not "liable as a seller;" and/or (3) is not "liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications." *Id.* § 1605(a)(1)-(3).

Under the BAAA's motion to dismiss procedures, when ruling on a motion to dismiss, the court must rely solely on the pleadings and any affidavits submitted under §§ 1605(c)(2)(A) and (B). *See* 21 U.S.C. § 1605(c)(3). Thus, the Act allows courts to dismiss biomaterials suppliers from lawsuits prior to discovery. *Id.* at § 1605(c)(2)(A)-(B). Further, under § 1605(e), dismissal must be with prejudice.

DISCUSSION

In 1998, Congress enacted the BAAA with the aim of assuring "the continued supply of materials for lifesaving medical devices" through provisions insulating the suppliers of raw materials or component parts of medical devices from litigation. 21 U.S.C. § 1601 *et seq.* The BAAA protects parties who supply either raw materials or component parts for medical implants ("biomaterials suppliers") from the expenses of implant failure litigation by providing "expeditious procedures to dispose of unwarranted suits against the suppliers." 21 U.S.C. § 1601(15)(B). As noted above, one such procedure is a motion to dismiss, which a biomaterials supplier may file under 21 U.S.C. § 1605(a).

To prevail on a BAAA motion to dismiss, the Secant Defendants must demonstrate that they: (1) are "biomaterials supplier[s];" (2) are not manufacturers of the failed implant; (3) are not sellers of the failed implant; and (4) did not provide raw materials or component parts that failed to meet applicable contractual requirements or specifications. *Id.* at § 1605(a)(1)-(3). Under these motion to dismiss procedures, the Secant Defendants may meet this burden through the submission of affidavits. *Id.* at § 1605(c)(2). This Court must grant the motion with prejudice, unless: (1) Plaintiff submits a valid affidavit demonstrating that the Secant Defendants are not biomaterials suppliers; (2) the Court determines, based solely on the pleadings and the parties' affidavits, that one of the three limited exceptions to the BAAA's general rue of immunity may apply; or (3)

Plaintiff has not named the manufacturer as a party. *Id.* at § 1605(c)(3). Notably, Plaintiff has not submitted an affidavit but instead argues only that her pleading raises a question as to whether the Secant Defendants are biomaterials suppliers. The requirements noted above will be discussed separately.

The Secant Defendants Are Biomaterials Suppliers

The BAAA defines a "biomaterials supplier" as "an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant." 21 U.S.C. § 1602(1)(A). An "implant" is "a medical device that is intended by the manufacturer of the device to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days." *Id.* at § 1602(5)(A)(i). A "component part" is "a manufactured piece of an implant," including a piece that: "(i) has significant non-implant applications; and (ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant." *Id.* at § 1602(3).

In support of their motion to dismiss, the Secant Defendants submitted the affidavit of Karen M. West ("West Affidavit"), an officer of Secant Medical, Inc., to establish their entitlement to the immunity provided by the BAAA. The West Affidavit attests to the following:

- The Secant Defendants knit polypropylene filament (which has other uses) into a mesh that is later incorporated into implanted devices.
- These rolls of mesh knit are not completed devices but require additional manufacturing before the mesh can be incorporated into implantable devices.
- Ethicon must cut and shape the mesh, sterilize the pieces, and package those pieces with other components, such as the necessary surgical tools.

- These additional steps are not in the Secant Defendants' control; rather, they are in the control of Ethicon, the manufacturer of the finished products.

Notably, Plaintiff did not respond to the Secant Defendants' motion with any affidavit of her own, but rather has relied entirely upon the allegations in the long form complaint. The complaint, however, does not contradict the West Affidavit, but rather avers that Ethicon made further refinements to the mesh after the Secant Defendants' involvement, because "it is cut by Defendants Ethicon [. . .] and packaged for distribution." Based on the affidavit and the averments in the complaint, this Court finds that the Secant Defendants are "biomaterials suppliers" because the mesh they created was a component part used in the manufacture of the pelvic mesh devices underlying this litigation.

The Secant Defendants Are Not Manufacturers of Ethicon's Implants

A biomaterials supplier may be liable as a "manufacturer of the implant that allegedly caused harm to a claimant only if" it: (1) "registered or was required to register with the Secretary [of Health and Human Services] pursuant to [the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360] and the regulations issued under such section;" and (2) "included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360(j) of this title and the regulations issued under such section." 21 U.S.C. § 1604(b)(2)(A). A biomaterials supplier may also be liable as a manufacturer if it was required, but failed, to complete either of the above factors and "is the subject of a declaration issued by the Secretary." *Id.* at § 1604(b)(2)(B).

Here, based on the West Affidavit and the averments in the complaint, this Court finds that the Secant Defendants are not registered with the Secretary of the Department of Health and Human Services, nor are they required to be. (West Aff. ¶12). Further, the Secant Defendants are

not required to list, and have never listed, their rolls of mesh as a device. (*Id.*). The Secant Defendants, therefore, are not liable as manufacturers.[1]

The Secant Defendants Are Not Sellers of Ethicon's Implants

Under the BAAA, a biomaterials supplier may be liable as "a seller of the implant." A "seller" is defined as "a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce." 21 U.S.C. § 1602(10). A biomaterials supplier may be liable as a seller only if it (1) "held title to the implant and then acted as the seller of the implant after its initial sale by the manufacturer" or (2) "acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant." *Id.* at § 1604(c)(1)(A)-(B).

Based on the West Affidavit and the averments in the complaint, this Court finds that the Secant Defendants did not market, promote, sell, package, or distribute the pelvic mesh implants. (West at ¶¶ 6, 14, 15). As such, the Secant Defendants are not liable as sellers under the BAAA.[2]

Contractual Requirements or Specifications

Under the BAAA, a biomaterials supplier may "be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence," that the biomaterials supplier "fail[ed] to meet applicable contractual requirements or specifications." *Id.* at § 1604(d). Additionally, the failure to meet the contractual specifications must be "an actual and proximate cause of the harm to the claimant." *Id.* at § 1604(d)(2). The Secant Defendants' mesh for the pelvic mesh implants was manufactured in accordance with

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[1] Notably, Plaintiff does not argue in her response that the Secant Defendants are manufacturers of the implants at issue.

[2] Notably, Plaintiff does not argue in her response that the Secant Defendants are sellers of the implants at issue.

specifications provided by Ethicon. (West Aff. ¶ 5). Furthermore, Plaintiff's complaint makes no allegations against the Secant Defendants that the mesh they produced failed to meet Ethicon's contractual requirements or specifications. Therefore, Plaintiff has failed to meet its burden to show that the mesh failed to meet Ethicon's contractual requirements or specifications.

In sum, based on the West Affidavit and the averments in the complaint, this Court finds that the Secant Defendants are biomaterials suppliers under the BAAA. Further, they were not the manufacturer or seller of the device, nor did they furnish raw materials or component parts that failed to meet contractual requirements or specifications. Thus, as biomaterials suppliers, the Secant Defendants are not liable for Plaintiff's alleged harm.

CONCLUSION

For the reasons stated herein, Plaintiff's claims against the Secant Defendants are barred by the immunity provided by the BAAA. Accordingly, the Secant Defendants' motion to dismiss is granted, and Plaintiff's claims are dismissed with prejudice pursuant to 21 U.S.C. § 1605. An Order consistent with this Memorandum Opinion follows.

NITZA I. QUIÑONES ALEJANDRO, J.